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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,740	12/02/2003	Ronald Adams	6530.0067-02	2077
22852	7590	07/29/2005		
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			EXAMINER FLANAGAN, BEVERLY MEINDL	
			ART UNIT 3739	PAPER NUMBER

DATE MAILED: 07/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/724,740

Applicant(s)

ADAMS ET AL.

Examiner

Beverly M. Flanagan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-51 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 25-51 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.


BEVERLY M. FLANAGAN
PRIMARY EXAMINER

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/2/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☒ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed December 2, 2003 has been made of record and the references cited therein have been considered by the examiner.

Preliminary Amendment

The preliminary amendment filed December 2, 2003 has been entered and made of record. Accordingly, the status of the claims is as follows: Claims 1-24 are canceled; claims 25-51 are newly added.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-51 are rejected under the judicially created doctrine of double patenting over claims 1-10 of U. S. Patent No. 6,761,685 and claims 1-17 of U.S. Patent No.

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6,179,776 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: a sheath apparatus comprising an elongated sheath with a lumen adapted to be positioned around an endoscope so as to permit the lumen to move longitudinally in relation to the endoscope and extend beyond a distal tip of the endoscope, the lumen having a deflectable distal end and a controller device for deflecting the distal end, where the controller device resides substantially parallel to the walls of the sheath.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

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only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 25-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Komiya (U.S. Patent No. 4,245,624).

Komiya shows a sheath apparatus for use with an endoscope (2), the sheath apparatus comprising: a flexible elongated sheath (1) for surrounding an endoscope (2), the sheath having a flexible lumen (5) extending within the sheath (1) and adjacent to the endoscope (2) so as to permit the lumen (5) to move in relation to the endoscope and beyond a distal tip of the endoscope (Fig. 3), the lumen having a deflectable distal end (col. 3, lines 1-4); and a controller device (96) residing adjacent a wall of the lumen (Fig. 10) extending beyond the distal tip, and connected to the distal end of the flexible lumen (5) for controlling deflection of the distal end of the lumen (col. 3, lines 15-18); wherein the flexible lumen is configured to allow delivery of surgical tools to an operating site (col. 3, lines 28-32). Komiya further shows said controller device including a flexible elongate member (6) extending from the proximal end to the distal end (Fig. 2) of the lumen (5), the flexible elongated member being eccentrically attached to the lumen (col. 2, lines 57-60), where retraction of the elongated member in the proximal direction deflects the distal end of the lumen (col. 3, lines 1-4). Komiya further shows the method comprising the steps of: inserting the endoscopic device into a body cavity of a patient; maneuvering the endoscopic device through the body cavity (98) and proximate to an operation site; extending a distal end of the lumen beyond a distal tip of the endoscope; and deflecting the extended distal end of the lumen to maneuver the

surgical tool; wherein the extending step includes advancing the proximal end of the lumen (5) in the distal direction (col. 2, lines 61-68 and col. 3, lines 1-42).

Claims 25-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Sachdeva et al. (U.S. Patent No. 5,607,435).

Sachdeva shows a sheath apparatus for use with an endoscope, the sheath apparatus comprising: a flexible elongated sheath (polymeric jacket 74) for surrounding an endoscope (14), the sheath having a flexible lumen (42) extending within the sheath (74) and adjacent to the endoscope (14) so as to permit the lumen to move in relation to the endoscope and beyond a distal tip of the endoscope (Fig. 4), the lumen having a deflectable distal end (col. 9, lines 3-9); and a controller device (delivery tube 50) residing adjacent the walls of the lumen extending beyond the distal end of the endoscope and connected to the distal end of the flexible lumen (42) for controlling deflection of the distal end of the lumen; wherein the flexible lumen is configured to allow the delivery of surgical tools to an operating site (suture thread 52); and the lumen is comprised of a flexible plastic material (polymeric material). Sachdeva et al. further show the method comprising the steps of: inserting the endoscopic device into a body cavity of a patient; maneuvering the endoscopic device through the body cavity and proximate to an operation site; extending a distal end of the lumen (42) beyond a distal tip of the endoscope (14); and deflecting the extended distal end of the lumen to maneuver the surgical tool; wherein the extending step includes advancing the proximal end of the lumen (42) in the distal direction.

Claims 25-51 are rejected under 35 U.S.C. 102(e) as being anticipated by Yoon (U.S. Patent No. 6,066,090).

Yoon shows a sheath apparatus for use with an endoscope, the sheath apparatus comprising: a flexible elongated sheath (42) for surrounding an endoscope (44), the sheath having a flexible lumen (46) extending within the sheath (42) and adjacent to the endoscope (44) so as to permit the lumen to move in relation to the endoscope and beyond a distal tip of the endoscope (Fig. 4), the lumen having a deflectable distal end (col. 5, lines 59-66); and a controller device (pull wire; col. 6, lines 5-12) residing in the walls of the lumen extending beyond the distal end of the endoscope and connected to the distal end of the flexible lumen (46) for controlling deflection of the distal end of the lumen; wherein the flexible lumen is configured to allow the delivery of surgical tools to an operating site (col. 6, lines 63-64). Yoon further shows the method comprising the steps of: inserting the endoscopic device into a body cavity of a patient; maneuvering the endoscopic device through the body cavity and proximate to an operation site; extending a distal end of the lumen beyond a distal tip of the endoscope; and deflecting the extended distal end of the lumen to maneuver the surgical tool; wherein the extending step includes advancing the proximal end of the lumen in the distal direction (col. 6, line 59 to col. 7, line 3).

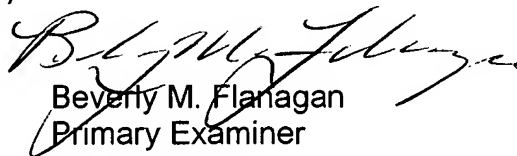
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Beverly M. Flanagan whose telephone number is (571)

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272-4766. The examiner can normally be reached on Mondays, Tuesdays and Thursdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Beverly M. Flanagan
Primary Examiner
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